

AO 120 (Rev. 3/2004)

TO: Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	<b>REPORT ON THE          FILING OR DETERMINATION OF AN          ACTION REGARDING A PATENT OR          TRADEMARK</b>
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In Compliance with 35 § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been  
 filed in the U.S. District Court Western District of Michigan on the following ☒ Patents or ☐ Trademarks:

DOCKET NO. <b>1:08-cv-00539</b>	DATE FILED <b>6/6/08</b>	U.S. DISTRICT COURT Western District of Michigan - at Kalamazoo
PLAINTIFF <b>Medicis Pharmaceutical Corporation</b>		DEFENDANT <b>Perrigo Israel Pharmaceuticals, Ltd., et. al.</b>
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 see attached		
2 <b>6,765,001</b>		
3 <b>7,220,424</b>		
4		
5		

In the above—entitled case, the following patent(s) have been included:

DATE INCLUDED	INCLUDED BY	<input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
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In the above—entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT
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CLERK <b>RONALD C. WESTON, SR.</b>	(BY) DEPUTY CLERK By <b>/s/ bd</b>	DATE <b>6/12/08</b>
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-Continued on Page 2-

**FILED - LN**

June 6, 2008 4:35 PM

RONALD C. WESTON, SR., CLERK  
U.S. DISTRICT COURT  
WESTERN DISTRICT OF MICHIGAN  
BY: *[Signature]*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MICHIGAN**

\_\_\_\_\_  
)  
)  
MEDICIS PHARMACEUTICAL CORPORATION, )  
)

Plaintiff, )  
)

v. )  
)

)  
)  
PERRIGO ISRAEL PHARMACEUTICALS, LTD., )  
)  
AND PERRIGO COMPANY, )  
)

Defendants. )  
)  
)  
)  
)  
)  
\_\_\_\_\_

**1:08-cv- 539**

**Paul L. Maloney**

**United States District Judge**

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

For its Complaint, Plaintiff Medicis Pharmaceutical Corporation ("Medicis")  
alleges as follows:

**PARTIES**

1. Medicis is a Delaware corporation with its principal place of business in Scottsdale, Arizona. Medicis is the leading independent specialty pharmaceutical company in the United States focusing primarily on the treatment of dermatological and podiatric conditions and aesthetics medicine. Medicis has developed and commercialized leading branded prescription products in a number of therapeutic categories. Medicis's products have earned wide acceptance by both physicians and patients due to their clinical effectiveness and high quality.

2. On information and belief, Defendant Perrigo Company has offices in the Western District of Michigan, with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

3. On information and belief, Defendant Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo Israel") is a company organized and existing under the laws of Israel having its principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

4. On information and belief, Perrigo Israel is a wholly owned subsidiary of Perrigo Company.

5. On information and belief, Perrigo Israel is controlled and/or dominated by Perrigo Company.

6. On information and belief, Perrigo Company conducts operations through international subsidiaries, including Perrigo Israel.

#### **JURISDICTION AND VENUE**

7. This action arises under the patent laws of the United States of America, Title 35, United States Code and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Perrigo Company because Perrigo Company resides in this judicial district and engages in continuous and systematic contacts within the Western District of Michigan.

9. This Court also has personal jurisdiction over Perrigo Israel because Perrigo Israel has expressly consented to jurisdiction within this district, and has designated Andrew M. Solomon (Assistant General Counsel of Perrigo Company) to accept service of this Complaint.

10. On information and belief, Perrigo Israel acts under the direction, control and influence of Perrigo Company with respect to the acts and conduct alleged in this Complaint.

11. For all of the reasons set forth above, this Court has personal jurisdiction over Perrigo Company and Perrigo Israel.

12. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b), because Perrigo Company and Perrigo Israel employ individuals in this judicial district and have offices and facilities in this judicial district, and thus purposefully avail themselves of the privilege of conducting activities within this judicial district.

#### **BACKGROUND**

13. On July 20, 2004, United States Letters Patent No. 6,765,001 (the "'001 patent") duly and legally issued to inventors Eugene H. Gans and Mitchell S. Wortzman, entitled "COMPOSITIONS AND METHODS FOR ENHANCING CORTICOSTEROID DELIVERY." A copy of the '001 patent is attached as Exhibit 1.

14. On May 22, 2007, United States Letters Patent No. 7,220,424 (the "'424 patent") duly and legally issued to inventors Eugene H. Gans and Mitchell S. Wortzman, entitled "COMPOSITIONS AND METHODS FOR ENHANCING CORTICOSTEROID DELIVERY." A copy of the '424 patent is attached as Exhibit 2.

15. Medcis owns the '001 and '424 patents.

16. Medcis has an approved New Drug Application ("NDA") No. 21-758 for fluocinonide cream 0.1%, which is sold under Medcis's trademark VANOS®.

17. Medici's VANOS® Cream is extremely successful and is widely used in the Western District of Michigan, the United States, and throughout the world to treat psoriasis, atopic dermatitis, and corticosteroid responsive dermatoses.

18. The claims of the '001 and '424 patents cover Medici's VANOS® Cream, and therefore, Medici submitted both the '001 and '424 patents to the United States Food and Drug Administration ("FDA") for listing in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (the "Orange Book"). The FDA has listed both the '001 and '424 patents in the Orange Book publication.

19. On information and belief, Perrigo Israel, at the direction of Perrigo Company, has filed Abbreviated New Drug Application ("ANDA") No. 90-256 with the Food and Drug Administration ("FDA"), for generic fluocinonide cream 0.1%. Perrigo Israel's ANDA contains a certification of invalidity, unenforceability, and/or noninfringement of the '001 patent. Notice of that certification, but not the certification itself, was transmitted to Medici on or after April 24, 2008, and was received by Medici on April 25, 2008.

20. Perrigo Israel had no adequate good faith basis for filing its ANDA No. 90-256 containing a certification of the alleged invalidity, unenforceability, and/or noninfringement of the claims of the '001 patent.

21. Perrigo's notice of certification was silent with regard to the '424 patent, which is also listed in the Orange Book for VANOS® Cream.

22. Medici repeatedly communicated with Perrigo Israel's outside counsel so Medici could confidentially review and evaluate Perrigo Israel's ANDA with regard to not only the '001 patent, but also the '424 patent. Although Medici made reasonable efforts to determine the actual content of Perrigo Israel's ANDA before filing this Complaint, neither Perrigo

Company nor Perrigo Israel agreed to provide Medicis confidential access to the ANDA under reasonable terms.

23. On information and belief, Perrigo Israel and Perrigo Company were aware of the '001 and '424 patents.

24. Perrigo Israel filed its ANDA for generic fluocinonide cream 0.1% because both Perrigo Israel and Perrigo Company, through its subsidiary, seek to enter the lucrative fluocinonide cream 0.1% market that VANOS® Cream pharmaceutical products have created by providing very beneficial and advantageous treatments for psoriasis, atopic dermatitis, and corticosteroid responsive dermatoses.

25. Perrigo Company actively and knowingly aided and abetted Perrigo Israel's filing of its ANDA seeking approval to market generic copies of Medicis's VANOS® Cream pharmaceutical products. Indeed, Perrigo Company has designated one of its Assistant General Counsels to accept service of this Complaint on behalf of Perrigo Israel.

### COUNT I

26. Each of the preceding paragraphs 1-25 is incorporated as if fully set forth herein.

27. Perrigo Israel filed its ANDA No. 90-256 to obtain approval under the Federal Food, Drug, and Cosmetic Act to market a pharmaceutical drug product as claimed in the '001 patent before the expiration of the '001 patent. On information and belief, Perrigo Israel has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

28. Perrigo Israel seeks approval to market generic fluocinonide cream 0.1% under ANDA 90-256 before the expiration of the '001 patent, while aware of the existence of the '001 patent and that the submission of the ANDA constitutes an act of infringement.

29. Perrigo Israel acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '001 patent.

### COUNT II

30. Each of the preceding paragraphs 1-25 is incorporated as if fully set forth herein.

31. Perrigo Israel filed its ANDA No. 90-256 to obtain approval under the Federal Food, Drug, and Cosmetic Act to market a pharmaceutical drug product as claimed in the '424 patent before the expiration of the '424 patent. On information and belief, Perrigo Israel has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

32. Perrigo Israel seeks approval to market generic fluocinonide cream 0.1% under ANDA 90-256 before the expiration of the '424 patent, while aware of the existence of the '424 patent and that the submission of the ANDA constitutes an act of infringement.

33. Perrigo Israel acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '424 patent.

### COUNT III

34. Each of the preceding paragraphs 1-29 is incorporated as if fully set forth herein.

35. When Perrigo Company actively and knowingly aided and abetted Perrigo Israel with the filing of its ANDA seeking approval to market generic fluocinonide cream 0.1%, Perrigo Company was aware of the '001 patent and knew that Perrigo Israel's submission of its ANDA constitutes an act of infringement. On information and belief, Perrigo Company has committed an act of patent infringement under 35 U.S.C. § 271(b).

36. Perrigo Company acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '001 patent.

**COUNT IV**

37. Each of the preceding paragraphs 1-33 is incorporated as if fully set forth herein.

38. When Perrigo Company actively and knowingly aided and abetted Perrigo Israel with the filing of its ANDA seeking approval to market generic fluocinonide cream 0.1%, Perrigo Company was aware of the '424 patent and knew that Perrigo Israel's submission of its ANDA constitutes an act of infringement. On information and belief, Perrigo Company has committed an act of patent infringement under 35 U.S.C. § 271(b).

39. Perrigo Company acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '424 patent.

**REQUESTED RELIEF**

WHEREFORE, Plaintiff Medicis respectfully seeks the following relief:

a. That judgment be entered that Defendant Perrigo Israel has infringed the '001 and '424 patents by submitting its ANDA;

b. That judgment be entered that Defendant Perrigo Company has infringed the '001 and '424 patents by inducing Perrigo Israel's infringement of the '001 and '424 patents through actively and knowingly aiding and abetting Perrigo Israel's filing of its ANDA;

c. That a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Defendants Perrigo Israel and Perrigo Company, their officers, agents or attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any therapeutic composition, or method of use covered by the '001 and '424 patents for the full term thereof, and from inducing or contributing to such activities;



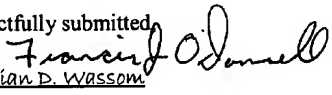
d. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of the ANDA be a date which is not earlier than the expiration of the '001 and '424 patents;

e. That this is an exceptional case under 35 U.S.C. § 285, and that judgment be entered for costs and reasonable attorneys fees to be awarded to Medicis; and

f. That this Court award such other and further relief as the Court may deem proper and just under the circumstances.

Date: June 6, 2008

Respectfully submitted,

*for*  *84 81 26 am*  
/s/ Brian D. Wassom

Brian D. Wassom  
Honigman Miller Schwartz and Cohn LLP  
Attorneys for Plaintiff  
2290 First National Building  
Detroit, MI 48226  
(313) 465-7594  
bdw@honigman.com  
P60381

Of counsel:

Matthew D. Powers  
Weil, Gotshal, & Manges, LLP  
201 Redwood Shores Parkway  
Redwood Shores, CA 94065  
Matthew.Powers@weil.com  
(650) 802-3000

Nicolas G. Barzoukas  
Jason C. Abair  
John R. Lane  
Weil, Gotshal & Manges, LLP  
700 Louisiana, Suite 1600  
Houston, TX 77002  
(713) 546-5062  
Nicolas.Barzoukas@weil.com  
Jason.Abair@weil.com  
John.Lane@weil.com